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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,870	02/15/2000	Charles S. Vann	0550-0076.30	6464

22896 7590 04/02/2002

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EXAMINER
BEX, PATRICIA K

ART UNIT	PAPER NUMBER
1743	13

DATE MAILED: 04/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

A8-13

Office Action Summary	Application N .	Applicant(s)	
	09/506,870	VANN ET AL.	
	Examiner	Art Unit	
	P. Kathryn Bex	1743	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 48-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 48-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4-5 7-8*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The cancellation of claims 26-47 and the addition of claims 48-62 is acknowledged and has been entered into the record.

Election/Restriction

2. Applicant's election without traverse of Group I., claims 1-25, 48-50 in Paper No. 12 is acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17, 21-25, 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21, terms "large" and "small" are relative terms which render the claim indefinite. The terms "large" and "small" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to what Applicant considers "large" or "small" openings. Same deficiency was found in claims 17, 22-23, 51, 55-57.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-9, 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin *et al* (WO 97/40383) in view of Ikeda *et al* (JP 64-80862) or Sakai *et al* (USP 4,937,048).

Gavin *et al* teaches a system for picking up a plurality of submillimeter beads 12 comprising a plurality of projections 16, 48 depending from a support 36 at spaced-apart location defining an array, an attraction source 56, operable at the projection end regions, effective to draw beads from the supply 10 and a plurality of ampules 80 or 82 for containing the bead supply disposed in an array alignable with the projection array (pages 15, line 12- page 17, line 19, Figs. 1-10). Gavin *et al* fail to disclose the use of a cavity formed at a lower end region of each of the projections, each of the cavities defined by a lower opening and an upper ceiling region, and a sidewall extending between the lower opening and the upper ceiling region. Ikeda *et al* do teach a cavity 2a formed at a lower end region of each of the projections 8, each of the cavities defined by a lower opening and an upper ceiling region, and a sidewall extending between the lower opening and the upper ceiling region to hold the beads 6 in the cavities and releasable retain them therein (Figs 3-4). Note: Ikeda *et al* teach the use of a plurality of projections in Figure 5. Similarly, Sakai *et al* teach an elastic cavity, i.e. carrier holding member 217, 124 formed at a lower end region of a suction nozzle 122, 218 each of the cavities defined

by a lower opening and an upper ceiling region, and a sidewall extending between the lower opening and the upper ceiling region to hold the beads 127,212 in the cavities and releasable retain them therein (Figs 11A, 13).

Since the arm is moved up and down with respect to the reaction vessel and the carrier is removed from the reaction tube by the carrier holding member arranged at the tip portion of the arm, it is possible to remove accurately the carrier contained in the reaction vessel even if the reaction vessel has a different shape (column 7, lines 39-45 of Sakai *et al*).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Gavin the cavity region, as taught by Ikeda *et al* or Sakai *et al*, in order to allow for greater contact between the lower end region of the projection supplying the suction source and the bead, thereby lowering the chance of dropping the bead prematurely.

In regard to the specific diameter openings, both Ikeda *et al* and Sakai *et al* disclose the claimed invention except for the lower opening diameters and the longitudinal length of the sidewall. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the lower opening of the cavity from between 100-1,250 micrometers and the longitudinal length of the sidewall from about 0.5-1.25 times the diameter of the lower opening, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin *et al* (WO 97/40383) in view of Ikeda *et al* (JP 64-80862) or Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Ekenberg *et al* (USP 5,272,510).

Gavin *et al*, Ikeda *et al* and Sakai *et al* as discussed above, fail to teach a support which is held by a frame that is adapted to pivot about a vertical axis, rendering movable the projection array along a generally arcuate or circular pathway, and adapted for reciprocal linear motion along a generally vertical pathway, wherein such movement permits the projections to be aligned with the ampule array and lowered so that each projection can enter a respective one of the ampules. Ekenberg does teach a support 30 which is held by a frame 32 that is adapted to pivot about a vertical axis, rendering movable the projection array 28 along a generally arcuate or circular pathway, and adapted for reciprocal linear motion along a generally vertical pathway, wherein such movement permits the projections to be aligned with the ampule array 24 and lowered so that each projection can enter a respective one of the ampules (cols. 8-9, Figs. 2, 7). The use of such a pivotal frame comprising the projections allows for the separation of the magnetic particles from the test media to be carried out simultaneously or sequentially, as desired (col. 8, lines 29-32).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Gavin *et al*, Ikeda *et al* or Sakai *et al* a pivotal frame, as taught by Ekenberg, in order to allow for the separation of the magnetic particles from the test media to be carried out simultaneously or sequentially, as desired.

9. Claims 19-20, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin *et al* (WO 97/40383) in view of Ikeda *et al* (JP 64-80862) or Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Hassler *et al* (WO 97/38318).

Gavin *et al*, Ikeda *et al* and Sakai *et al* as discussed above, fail to teach a detection system having a field of view extending along each of the projection end regions and adapted to sense the presence or absence of a bead retained in the cavity. Hassler *et al* do teach system for counting beads 22 having a projection 15 with a lower end region, i.e. capillary, 2. Hassler *et al* disclose a detection system which includes a plurality of elongated light-conductive fibers 4, 6, each fiber having one end that extends along one of said projections and faces into said cavity, i.e. perpendicular to the longitudinal axis A of the capillary 2, and a second end disposed in optical communication via reflective surfaces 10, 11 with a camera 5 (pages 6-8, Figs. 1-2). As a result of the arrangement of the optical fibers parallel to the longitudinal axis A of the projection, the form of the device is very compact and space-saving. Moreover, such a robust construction provides that any movement or vibrations of the device will not impair the propagation of the measuring light along the optical light path (page 10, 2nd full paragraph).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Gavin *et al*, Ikeda *et al* or Sakai *et al* with the optical system, as taught by Hassler *et al*, in order to form a device that is very compact and space-saving.

10. Claims 21-25, 55, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin *et al* (WO 97/40383) in view of Ikeda *et al* (JP 64-80862) or Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Kambara *et al* (USP 6,288,220).

Gavin *et al*, Ikeda *et al* and Sakai *et al* as discussed above, fail to teach a conduit assembly having a plurality of conduits for separately channeling a plurality of beads released from the cavities to desired locations on a substrate, the conduits having large openings at their upper ends disposed in an array having a center-to-center pitch like that of the projection array such the large openings are substantially alignable under the projections, and small openings at their lower ends in array having a center-to-center pitch like that of the substrate array. Kambara *et al* do teach a plurality of conduits 36 for separately channeling a plurality of beads released from the transfer device to desired locations on a substrate 34, the conduits having large openings at their upper ends disposed in an array having a center-to-center pitch like that of the projection array such the large openings are generally alignable thereunder, and small openings at their lower ends. Additionally, wherein the conduits slope inwardly along the longitudinal axis (Fig. 8A). Moreover, Kambara *et al* teach use of a laser cast on the plurality of conduits in direction parallel to the plate on which the conduits are arrayed and detecting the fluorescence emitted in each conduit with a two-dimensional detector, i.e. CCD (column 12, line 15- column 13, lines 41). The use of the conduits assures that the bead will fall into the proper test receptacle well and thereby eliminates the problem of transfer and delivery of the units between the transfer device and the test receptacle tray when the tray has been miniaturized.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Gavin *et al*, Ikeda *et al* and Sakai *et al*, a plurality of conduits, as taught by Kambara *et al*, in order to assure that the bead will fall into the proper test receptacle well and thereby eliminates the problem of transfer

and delivery of the units between the transfer device and the test receptacle tray when the tray has been miniaturized.

11. Claims 21-24, 51, 54, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin *et al* (WO 97/40383) in view of Ikeda *et al* (JP 64-80862) or Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Carre *et al* (EP 955 084 A1).

Gavin *et al*, Ikeda, and Sakai *et al* as discussed above, fail to teach a conduit assembly having a plurality of conduits for separately channeling a plurality of beads released from the cavities to desired locations on a substrate, the conduits having large openings at their upper ends disposed in an array having a center-to-center pitch like that of the projection array such the large openings are generally alignable thereunder, and small openings at their lower ends. Carre *et al* do teach a plurality of conduits 12 for separately channeling a plurality of beads (column 12, lines 15-54) released from the transfer device (column 11, lines 10-14) to desired locations on a substrate 66, the conduits having large openings at their upper ends disposed in an array having a center-to-center pitch like that of the projection array such the large openings are generally alignable thereunder, and small openings at their lower ends and wherein the conduits are curve along the longitudinal axis (abstract, Fig. 8). The use of the conduits allows for a very flexible transfer system which can deliver beads from a multi-well plate having any number of wells to a plate having a large number of wells per area (column 21, line 48-58).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Gavin *et al*, Ikeda *et al* and Sakai *et al* a plurality of conduits, as taught by Carre *et al*, in order allow for the transfer of

beads from a multi-well plate having any number of wells to a plate having a large number of wells per area (column 21, line 48-58).

12. Claims 21 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin *et al* (WO 97/40383) in view of Ikeda *et al* (JP 64-80862) or Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Gilford *et al* (USP 4,236,825).

Gavin *et al*, Ikeda, and Sakai *et al* as discussed above, fail to teach the conduit assembly supported by a parallelogram linkage assembly for reciprocal arcuate movement between a raised position and a lowered position. However, Gilford *et al* do teach an elevator assembly 78 comprising a plurality of conduits 87 which is swingably supported on wall member 71 by rod elements 79 and 80 defining a parallelogram linkage whereby as the coupler block 42 engages and pushes against roller 73, the tube carrier arm 75 is arcuately swung while maintaining its horizontal position downwardly from its FIG. 7 position and in the "in direction" of the trackway 15 to its FIG. 8 position (column 5, line 58- column 6, line 9).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Gavin *et al*, Ikeda *et al* and Sakai *et al* a plurality of conduits supported by a parallelogram linkage assembly, as taught by Gilford *et al*, in order provide automated and precise alignment of the individual conduits with each reaction well.

13. Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin *et al* (WO 97/40383) in view of Ikeda *et al* (JP 64-80862) or Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Gorlich *et al* (USP 5,447,736).

Gavin *et al*, Ikeda *et al*, and Sakai *et al* as discussed above, fail to teach a covering system comprising a continuous web of cover material mounted for movement from a supply position to a take-up position, a shearing blade mounted for reciprocal linear motion along a direction substantially normal to the web for cutting the cover material at a region between the supply position and the take-up position. Gorlich *et al* do teach a covering system comprising a continuous web of cover material mounted for movement from a supply position 30 to a take-up position 32, a shearing blade 35 mounted for reciprocal linear motion along a direction substantially normal to the web for cutting the cover material at a region between the supply position and the take-up position (col. 4, line 61- col. 5, line 9, Fig. 3). Such use of a covering means allows insures that the contents of the container will maintain an inert atmosphere until needed.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Gavin, Ikeda *et al* and Sakai *et al*, a covering mean, as taught by Gorlich, in order to assure the container will maintain an inert atmosphere until needed.

Allowable Subject Matter

14. Claims 53 and 56 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to teach or suggest a system of aspirating a plurality of beads from a supply comprising a carousel pivotally supporting a conduit assembly formed on a parallelogram

linkage support and having a substrate holding area adjacent to the parallelogram linkage assembly. The system further comprising a stationary rail extending along an inner region of the carousel and having a bearing surface for lifting the parallelogram linkage assembly relative to the substrate.

Conclusion

16. No claims allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 or (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

P. Kathryn Bex
Patent Examiner
AU 1743
March 26, 2002

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